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EXAMINER	
SONNETT, KATHLEEN C	
ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,952	JAGGER ET AL.	
	Examiner	Art Unit	
	KATHLEEN SONNETT	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/26/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 21-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-30 are pending. Claims 1-8 and 21-30 are withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 9 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt (US 6,948,223) in view of Morales (US 5,920,975). Shortt discloses a method for fabricating a balloon catheter stent deployment system comprising:

- providing a balloon catheter with an inner tubular shaft disposed within an outer tubular shaft, the inner and outer shafts each having proximal and distal ends, the distal end of the inner shaft extending distally beyond the distal end of the outer shaft, and an inflatable balloon having a proximal end attached to the outer shaft near the distal end thereof and a distal end attached to the inner shaft near the distal end thereof (see fig. 2)

- placing a stent over the balloon so that a distal end of the stent is disposed proximally to the distal end of the balloon leaving a distal section of the balloon uncovered by the stent and a proximal end of the stent is spaced distally from the proximal end of the balloon leaving a proximal section of the balloon uncovered by the stent that extends from the proximal end of the stent to the proximal end of the balloon

- crimping the stent to leave the stent with initial outer diameter (col. 2 ll. 17)

- placing a stepped enclosure over the stent and balloon wherein the stepped enclosure comprising a first section (2nd TFE) having a first inner diameter and that is connected to

a second section (3rd Center TFE) having a second inner diameter, the first inner diameter being greater than or equal to the second inner diameter, the second inner diameter being greater than the initial outer diameter of the stent but in close approximation thereto, the second section of the stepped enclosure being longer than the stent, and wherein the first section of the stepped enclosure is disposed over the proximal section of the balloon and the second section of the stepped enclosure is disposed over the stent and the disatl section of the balloon (col. 2 ll. 12-42),

- inflating the balloon so that the proximal section of the balloon inflates and engages the first section of the stepped enclosure and the stent and a portion of the balloon disposed beneath the stent and the distal section of the balloon are prevented from substantial expansion by the second section of the stepped enclosure (see proximal pillow gap), and the maximum outer diameter of the distal section of the balloon is no greater than the initial outer diameter of the stent

-removing the balloon and stent from the stepped enclosure (col. 2 ll. 40-42).

4. The distal section of the balloon can be considered the portion of the balloon that is beneath the "4th TFE" in fig. 2. This distal section has a diameter smaller than the initial diameter of the stent. The "4th TFE" may be considered part of the second section of the stepped enclosure since it is not required that the second section has a continuous inner diameter. The second section prevents substantial expansion of the distal end of the balloon.

5. Shortt fails to disclose crimping the stent onto the balloon as the step of crimping is done prior to the stent being placed over the balloon according to the disclosure of Stiles. However, as taught by Morales, it is old and well known to first place a stent onto a balloon and then crimp the stent onto the balloon (col. 1, ll. 55-61). Crimping a stent onto a balloon prevents the stent from sliding off the catheter when the catheter is advanced through the patient's vasculature.

Crimping the stent after it has been placed onto the balloon has the obvious advantage of being able to more tightly fit the stent onto the balloon as opposed to sliding a crimped stent onto a balloon. Therefore, such a modification to the method of Shortt would have been obvious to one skilled in the art in view of Morales.

6. Regarding claim 13, the stepped enclosure is a stepped tube and the second section of the stepped tube extends into the first section of the stepped tube to provide an overlap section between the two sections (see fig. 2).

7. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt in view of Morales as applied to claim 9 above and further in view of Euteneuer et al. (U.S. 5,147,302). Shortt discloses that the method substantially as stated above, but fails to disclose flaring the ends of the stepped tube enclosure.

8. However, Euteneuer et al. discloses that it is old and well known in the art to include flared ends on tubes (50) that are placed over a balloon in order to reduce abruptness of the leading edge of the tube (col. 4 ll. 7-15). Reduced abruptness allows for easier placement of the tube over the balloon. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Shortt to include flared ends on the stepped tube in order to facilitate placement of the stepped tube over the stent and balloon as made obvious by Euteneuer et al.

9. **Claims 9 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt in view of Morales. The following 103 rejections refer to the improved method disclosed by Shortt whereas the 103 rejections of claims 9 and 13 discussed above are based on the prior art that Shortt discloses as old and well known in the art in the background . Shortt in view of Morales discloses a method for fabricating a balloon catheter stent deployment system comprising:

- providing a balloon catheter (see fig. 7)

- placing a stent over the balloon (see fig. 7)

- crimping the stent onto the balloon to leave the stent with initial outer diameter (col. 2 ll. 54-55) as taught by Morales

- placing a stepped enclosure over the stent and balloon

10. In particular, Shortt discloses a stepped enclosure (see fig. 6). The stepped enclosure includes a second section that is at least as long as the stent with a second inner diameter that is greater than the initial outer diameter of the stent but in close approximation to thereto. The enclosure also includes a first portion that covers the proximal section of the balloon. Shortt does not expressly disclose that the diameter of this first portion is greater than or equal to the inner diameter of the second section. However, Shortt discloses that the channels of the mold may be made such that the channel includes sections for formations of a proximal pillow (col. 4 ll. 5-7 and 52-59). As seen in fig. 7a, the resulting balloon catheter stent deployment system has a proximal pillow. This would only result if the section of the mold channel that covers the proximal section of the balloon has a larger diameter than the section covering the stent. Shortt discloses applying pressure to the mold in order to secure the stent to the balloon (col. 2 ll. 60-61). The balloon then inflates and will be allowed to inflate in the section of the stepped enclosure where the diameter is larger, thereby forming the proximal pillow shown in fig. 7a. As shown in fig. 7a, the balloon is inflated so that the proximal section of balloon engages the first section of the stepped enclosure and the proximal end of the stent since the diameter just proximal of the proximal end of the stent is larger than the outer diameter of the stent. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Shortt to include providing a stepped enclosure comprising a first section covering the proximal section of the balloon, the first section having a diameter greater than the second section

disclosed by Shortt which covers the stent in order to achieve the configuration shown in fig. 7a. Regarding the distal section of the balloon having a maximum outer diameter no greater than the initial outer diameter of the stent, the diameter of a distal section of the balloon distal of the "distal pillow" is smaller than the initial diameter of the stent. It is noted that the portion of the stepped tube covering this distal section can be considered part of the second section of the stepped tube. As discussed above in more detail, Morales teaches first placing the stent onto the balloon and then crimping the stent onto the balloon.

11. Regarding claim 18, Shortt discloses the invention substantially as stated above but fails to disclose that the gas used to inflate the balloon has a temperature ranging from about 40º C to about 60º C. However, applicant has not disclosed that the temperature of the gas in the range from about 40˚ to about 60˚ C (in spec. 40˚ to 85˚ C) is used for a particular purpose or provides any advantage. Furthermore, applicant discloses in the instant specification that the gas may alternatively be delivered at ambient temperature with no disadvantage disclosed (p. 8 ll. 23-26 of instant specification). One of ordinary skill in the art would expect the method of Shortt using an ambient temperature to perform equally as well as applicant's claimed temperature range (40 to 60˚C) since no disadvantage is disclosed for using ambient temperature gas for inflation. Moreover, Shortt exposes the inflated balloon to an elevated temperature after inflation to help set the stent, and therefore the gas will reach this temperature. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Shortt to include the step of delivering gas having a temperature range from about 40˚ to about 60˚ C because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Shortt.

12. **Claims 10 and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt in view of Morales as applied to claim 9 above and further in view of Miraki et al. (U.S. 5,704,845). Shortt in view of Morales discloses the invention substantially as stated above, but fails to disclose inserting a protective sleeve over the stent after removing the balloon from the stepped enclosure.

13. However, Miraki et al. discloses that it is old and well known to house a balloon catheter in a protective sleeve (52) before use in order to keep the catheter sterile (col. 3 ll. 19-21). This protective sleeve is put on the finished catheter and is therefore placed over the catheter after the manufacturing process. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Shortt. to include inserting a protective sleeve over the stent as made obvious by Miraki et al. in order to keep the stent sterile. Miraki et al. does not disclose keeping the protective sleeve in a position proximal to the balloon prior to and during a manufacturing step and then sliding it over the balloon after the step is completed. However, applicant has not disclosed that keeping the sleeve pre-mounted on the catheter proximal to the stent and then sliding the sleeve over the stent after removing the stepped tube is used for any particular purpose, or provides any advantage. Furthermore one of ordinary skill in the art would expect the modified method of Shortt and applicant's claimed method to perform equally well using either a protective sleeve that is pre-mounted proximally of the stent and then slid over the stent or a protective sleeve that is slide over the stent from the distal end of the stent.

14. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt in view of Morales as applied to claim 9 above and further in view of Johnson (WO02/066095). Shortt in view of Morales discloses the invention substantially as stated above, but fails to disclose that the ends of the stepped tube are flared.

15. However, Johnson discloses that it is old and well known to flare ends of fold over molds used for forming balloon catheter stent deployment assemblies. Johnson discloses that flared edges further facilitate the placement of the assembly in the mold (see page 18 and fig. 9). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Shortt to include flared ends on the stepped enclosure as made obvious by Johnson in order to facilitate insertion of the assembly in the mold.

16. **Claims 14 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt in view of Morales as applied to claim 9 above and further in view of Motsenbocker et al. (U.S. 6,629,350). Shortt in view of Morales discloses the invention substantially as stated above, but fails to disclose the stepped enclosure (mold) being formed by a plurality of crimping elements each having a stepped leading edge to form the stepped enclosure that are capable of heating the stent and the balloon.

17. However, Motsenbocker et al. discloses that it is old and well known in the art to use a plurality of crimping elements, each having a stepped leading edge (col. 7 ll. 55-59), to form a stepped enclosure wherein the crimping elements are movable between crimping and retracted positions (see abstract). Motsenbocker et al. discloses that this device is superior to stepped tubes because the bore size of a stepped tube limits the diameter of the stent (col. 1 ll. 47 and 63+), which is avoided using the crimping elements. Furthermore, Motsenbocker et al. discloses that heaters may be placed in the crimping elements (col. 13, ll. 7-10) so that heat may be applied during crimping as is well known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Shortt to include a plurality of crimping elements with stepped edges that are capable of delivering heat as made obvious by Motsenbocker et al. to form the stepped enclosure (mold) in order to gain

the advantage of a changing bore size that allows a single mold to hold assemblies of varying diameters.

18. **Claims 16-17 and 19-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt in view of Morales as applied to claim 9 above and further in view of Jendersee et al. Regarding claims 16 and 17, Shortt in view of Morales discloses the method substantially as stated above but fails to disclose heating the stent and balloon to a temperature ranging from about 50° C to about 85° C degrees.

19. However, Jendersee et al. discloses that it is old and well known to heat a balloon catheter stent deployment assembly to about 65°C (150° F = 65.6° C) to set the assembly (col. 6 ll. 64-67). Although Shortt discloses heating the assembly to about 93° C, Shortt also discloses that the temperature to which the assembly is heated will depends on the materials being used (col. 4 ll. 38-41). Shortt is silent on the materials used for the assembly and if the materials of Jendersee such as a balloon formed of polyethylene terephthalate (PET) are employed using the method of Shortt, it would be obvious to one of ordinary skill in the art to modify the method of Shortt to include the step of heating the stent and balloon to a temperature of about 65° C as made obvious by Jendersee et al. in order to be able to form a balloon catheter stent assembly with the materials of Jendersee et al. using the method and mold of Shortt.

20. Regarding claim 19, Shortt discloses the method substantially as stated above including pressurizing the balloon (col. 2, ll. 60-61), but is silent on a pressure range and time period for the pressurizing step.

21. However, Jendersee et al. discloses that it is old and well known in the art to pressurize the balloon to an internal pressure ranging from about 30 to about 75psi (col. 6, line 64) during the setting of a balloon catheter stent deployment assembly. Since Jendersee et al. has

disclosed this range as being appropriate for setting of a balloon catheter stent deployment assembly, one of ordinary skill would be motivated to use this range to carry out the method of Shortt with a reasonable expectation of success. Jendersee et al. fails to disclose a time period for pressurizing the balloon ranging from 5 seconds to about 1 minute. However, applicant has not disclosed that pressurizing the balloon for a period ranging from 5 seconds to about 1 minute solves any stated problem, is used for any particular purpose, or provides any advantage. Moreover, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller,* 105 USPQ 233).

22. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Shortt such that the time period for pressurizing the balloon ranges from 5 seconds to about 1 minute because such a modification would have been considered a mere design consideration which fails to patentably distinguish over modified Shortt.

23. Regarding claim 20, Shortt discloses the invention substantially as stated above but fails to disclose inflating the balloon with a gas having a temperature ranging from about 40 to about 60° C and pressurizing the balloon to an internal pressure ranging from about 30° C to about 75° C for a time period ranging from about 5 seconds to about 1 minute.

24. However, Jendersee et al. discloses that it is old and well known in the art to pressurize the balloon to an internal pressure ranging from about 30 to about 75psi (col. 6, line 64) during the setting of a balloon catheter stent deployment assembly. Since Jendersee et al. has disclosed this range as being appropriate for setting of a balloon catheter stent deployment assembly, one of ordinary skill would be motivated to use this range to carry out the method of Shortt with a reasonable expectation of success. Jendersee et al. fails to disclose a time period

for pressurizing the balloon ranging from 5 seconds to about 1 minute. However, applicant has not disclosed that pressurizing the balloon for a period ranging from 5 seconds to about 1 minute solves any stated problem, is used for any particular purpose, or provides any advantage. Moreover, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller,* 105 USPQ 233). Regarding the temperature of the gas, applicant has not disclosed that the claimed range (about 40° to about 60° C) is used for a particular purpose or provides any advantage. Furthermore, applicant discloses in the instant specification that the gas may alternatively be delivered at ambient temperature with no disadvantage disclosed (p. 8 ll. 23-26 of instant specification). One of ordinary skill in the art would expect the method of Shortt using an ambient temperature to perform equally as well as applicant's claimed temperature range (40 to 60°C) since no disadvantage is disclosed for using ambient temperature gas for inflation. Moreover, Shortt exposes the inflated balloon to an elevated temperature after inflation to help set the stent. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Shortt to include the step of delivering gas having a temperature range from about 40° to about 60° C and a pressure of from about 30 to about 75 psi for from about 5 seconds to about 1 minute because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Shortt.

Response to Arguments

25. Applicant's arguments filed 6/26/2008 have been fully considered but they are not persuasive. Applicant argues that the sheaths 21 and 22 cannot serve as both the stepped enclosure and the inner and outer shafts. However, the examiner has used the TFE sheaths 21 and 22 as the stepped enclosure only. The inner and outer shafts are also shown in fig. 2, the

shafts being the two elements that the balloon is shown connected to. Applicant argues that Shortt does not disclose the balloon's proximal end being attached to an outer shaft of a catheter and the balloon's distal end being attached to an outer shaft of a catheter. The examiner respectfully disagrees as it would have been obvious to one skilled in the art that the stent delivery device mounted within the 4 TFE tubes shown in fig. 2 includes a balloon mounted on a catheter comprising two shafts.

26. Applicant also argues that Shortt fails to disclose the step of inflating the balloon so that the proximal section of balloon engages both the first section of the stepped enclosure and the stent (specifically arguing engagement with the stent). The proximal portion of the balloon may include the portion of the balloon labeled by the "max stent pillow gap" in fig. 2, which is adjacent to the proximal end of the stent. Upon inflation, this portion expands as shown in fig. 2 and engages the end surface of the stent since its diameter is now greater than the stent's outer diameter (also shown in fig. 2). In other words, fig. 2 shows room for inflation in the "max stent pillow gap" and introduction of inflation fluid into the balloon will result in this section inflating until it engages the surface second sheath (22, labeled as "3rd Center TFE"). Using the improved method taught by Shortt as discussed in the later rejections of claims 9 and 18, inflation of the balloon causes it to engage the first section of the stepped enclosure (causing the proximal pillow shown in fig. 7a) as well as the proximal end of the stent since the outer diameter of the balloon adjacent the proximal end of the stent has a larger diameter than the stent.

27. Applicant also argues that Shortt fails to disclose an inflated balloon with a distal section having a maximum outer diameter no greater than the initial outer diameter of the stent. However, as described in paragraph 6 of the office action mailed 3/26/2008, the distal section of the balloon can be considered the portion of the balloon that is beneath the "4th TFE" in fig. 2.

This distal section has a diameter smaller than the initial diameter of the stent. The "4th TFE" may be considered part of the second section of the stepped enclosure since it is not required that the second section has a continuous inner diameter. The distal section does not have to abut the distal end of the stent according to the current claim language.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 9/17/2008

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731